

REMARKS

The Examiner's action dated July 20, 2007, has been received, and its contents carefully noted.

The office action includes claim objections stating that claims 1-14 need to be renumbered. However, the office action refers to claims 1-15, from which it must be assumed that the Examiner has already renumbered the claims. It is noted that when the numbering of claims in an application is correct, renumbering is normally done by the Examiner. See, in this connection, MPEP 608.01(j), and in particularly form paragraph 6.17. In any event, in the present amendment, the claims are correctly numbered.

It is further noted that claims 3-6 have now been withdrawn from consideration. However, the original election of species requirement identified the elected Group III, as containing claims 1-2 and 5-14. It would appear that, in view of the reason giving for the election requirement, both of the claims originally numbered "5", now claims 5 and 6, should properly have been considered to be included within the elected group. Undersigned does not believe that the Examiner can ignore claims included in an elected group without issuing a new restriction requirement. Therefore, applicant is entitled to a first action on the merits of the claims currently numbered 5 and 6.

In order to advance matters, the application claims have been amended to more clearly define the contribution of the invention over the prior art and the prior art rejection is traversed at least for the reason that the novel structure now defined in the claims, and particularly in parent claim 1, is not disclosed in or suggested by any combination of the teachings of the applied references.

It should firstly be noted that the present invention is directed to a splint for immobilizing a body part and that neither of the applied references is directed to a splint, or to any device, that can immobilize a body part. In other words, both references are found in arts that are nonanalogous to the present invention and that are, moreover, nonanalogous to one another.

As stated by the CCPA in *In re Wood et al*, 202 USPQ 171 (1979) :

The determination that a reference is from a nonanalogous art is therefore two-fold. First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved.

In the present case, clearly, neither reference is from the field of the inventor's endeavor. Moreover, neither reference is in any way pertinent to the particular problem with which the inventor was involved, which was to provide a simple, versatile splint for immobilizing a body part. Neither reference discloses a device that having, or intended to have, such a function.

A splint according to the present invention is, as defined in claim 1, composed of tubes and non-inflatable parts that are made of a flexible material and constructed to be wrapped around the body part in a circumferential direction, while the tubes and non-inflatable parts extend in a direction transverse to the circumferential direction, which orientation is required to immobilize a body part.

The patent to Dye discloses a compression sleeve, the purpose of which is to increase blood flow velocity. The compression sleeve disclosed in this reference is not intended to immobilize a body part and is not capable of doing so.

Claim 1 specifies that the splint comprises inflatable tubes interconnected by non-inflatable parts, and that each of said non-inflatable parts is located to extend between two of said inflatable tubes. In contrast, the part 36 of the reference compression sleeve that the Examiner equates to the claimed non-inflatable parts do not

interconnect inflatable tubes. Rather, as shown in Figures 1 and 5 of the reference, sealing lines 36 are disposed along one edge of the sleeve and define outer edges of various inflatable parts. Parts that do interconnect inflatable parts, such as sealing lines 34, extend in a direction that corresponds to the circumferential direction, and not the transverse direction, defined in claim 1 of the present application. Sealing lines 34 prevent the compression sleeve from performing any immobilizing function.

Furthermore, claim 1 defines ventilation holes contained in the **non-inflatable** parts. In the reference device, apertures 44, which the Examiner equates to the claimed ventilation holes, are disposed in **inflatable** parts 42. Parts 42 are ventilation apertures in a channel 42 into which pressure rise air is introduced. The reference disclose that this air is forced through apertures 44 in order to perform a cooling function. It is clear from the illustration provided in Figure 6 of the reference that apertures 44 will be in direct contact with the body part being treated and it thus does not appear that very much air, if any, can be forced through those apertures. In any event, since the apertures are provided in inflatable parts 42, they do not expose the body part to the surrounding atmosphere, whereas ventilation holes that are contained in, and extend through, non-

inflatable parts, as now defined in application claim 1, will not directly contact the body part being treated and can thus perform a more effective ventilation function.

Of course, there is no evidence that one skilled in the art would have a reason to believe that the compression sleeve disclosed by Dye could be used, or modified, to serve as a splint for immobilizing a body part.

It is noted that the Simons patent was relied on only for its disclosure of a loop. This element has been deleted from application claim 1 because it is not believed necessary to distinguish over the prior art. In view of this deletion, it is believed that only the applicability of the Dye patent to amended claim 1 need be considered.

Application claim 3 specifies that the splint is constructed for immobilizing the torso. The Dye patent does not disclose a compression sleeve that is intended for, or capable of, such use and one skilled in the art would have no reason to consider modifying the device of that reference for such use.

Claim 4 similarly distinguishes over the reference by its recitation that the body part is the neck.

Claims 5 and 6, which are currently withdrawn but which, it is submitted, should have been examined with the claims of the elected species, clearly distinguish over the

applied references by their recitations that the body part is composed of the leg, the foot, the ankle and the heel (claim 5), or the arm, for immobilizing the shoulder joints or upper and lower arm (claim 6).

Claims 7 and 8 distinguish over the applied references by their recitations of nylon layers and a polyurethane coating. The Dye reference appears to mention only PVC as the material used for the compression sleeve and, contrary to the assertion presented in support of the rejection, no mention of either nylon or polyurethane has been found in that reference.

Claim 9 specifies that the body part is a limb having a limb articulation and that movement, rigidity and stabilization of the articulation is controlled by air pressure in the splint. It should be readily apparent that the compression sleeve disclosed by Dye is expressly intended to not have any effect on a limb articulation.

Claim 13 further distinguishes over the applied reference by its recitation of a suspension strap, which is element 70 shown in figure 6 of the application drawing. No component of this type is disclosed in either of the applied references.

Claim 15 distinguishes over the applied references by its recitation that the adjustable member is detachable.

Neither of the applied references discloses a detachable member.

New claim 16 further defines at least one loop connected for suspension purposes. This recitation originally appeared in claim 1, but is not believed necessary to distinguish that claim over the prior art. In the explanation of the rejection of claim 1, the Simons patent was asserted to disclose this feature.

As noted earlier herein, Simons is found in an art that is of no relevance to the subject matter of either the present invention or the primary reference.

One skilled in the art would have absolutely no reason to consider modifying the compression sleeve of Dye in accordance with any teaching relating to the coat-type garment disclosed by Simons. Furthermore, the loops 66 and 67 shown in Figure 3 of the Simons patent are described in the patent reference as hangers to permit the garment to be hung from a wall, door or the like. It should be readily apparent that one skilled in the art would have absolutely no reason to provide such loops in order to hang the compression sleeve of Dye from a wall, or door when it is not in use. Whereas the loop defined in claim 16 of the present application is provided to allow the splint to be suspended when it is performing its immobilizing function, there is nothing in the

disclosure of Dye to suggest that the compression sleeve is to be suspended when it is in use.

Claim 17 further distinguishes over the applied references by its recitation of the location of the loop.

Since the claims that have been withdrawn from consideration depend from claim 1, and claim 1 is believed to define patentably over the applied references, it would be appropriate to withdraw the election of species requirement, and allow all of the pending claims, and it is requested that this be done.

If the above amendment should not now place the application in condition for allowance, the Examiner is invited to call undersigned counsel to resolve any remaining issues.

Respectfully submitted,

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## Immobilizing and supporting inflatable splint apparatus

### FIELD OF THE INVENTION

The present invention relates to the field of medical devices, and, more particularly, it relates to inflatable versatile/universal multi purpose splints.

### BACKGROUND OF THE INVENTION

The traditional techniques of providing support and immobilization in orthopedic conditions revolves around three types of devices: casts, which have application primarily in broken limbs; splints, which are used to immobilize and stabilize the limbs and the torso; and pressure bandages, which help control swelling and give a degree of support.

Creative individuals have come up with a variety of departures from these standard themes in order to achieve better patient treatment. Inflatable pouches made from elastic materials exist, adapted to be filled with either liquid or gas, and incorporating means for securing these pouches to the injured part of a human body and tightening them around it. Splints of this kind effect the immobilization and compression of a limb or other part of a human body.

One of the alternative devices is presented in U.S. Pat. No. 5,954,676.

This device utilizes two sets of multi-layer deformable materials, such as fiberglass shims located in pouches in first and second members having re-sealable bladders of sheaths that provide structural support on each side of the limb.

The main drawback of the device, which limits its application considerably, relates to its fixed and inflexible shape that does not take into consideration the rounded form of the limbs, joints and the torso, for instance.

A different device is U.S. Pat No. 5,288,286, which is an adjustable pressure cast for orthopedic injuries. It is composed of three sets of air chambers and is only designed for treating orthopedic leg injuries such as fractures. As in the previous patent, this device suffers from an inconvenient structure, which may only support the calf, the ankle and the foot of a patient without conforming to the shape of these structures.

There is a need for a method and a concept for a light and convenient splint which adjusts to the shape of the limb, joints or any other body part in question and may also provides steady

support to the trunk (i.e. spine, ribs, neck etc.), while at the same time allowing free blood circulation, ventilation and enables medical inspection of the injured area.

SUMMARY OF THE INVENTION

In accordance with the shortcomings of previous art, it is a principal object of the present invention to provide a splint device which will present a maximum adjustment range, so it can be easily and securely fitted to the injured body part, without bringing about any uncomfortable chafing and minimize the overall discomfort, will also allow for adequate blood circulation to the injured part, and support the joints in an optimal position with a controllable measure of rigidity.

It is yet another object of the present invention to introduce a multi purpose splint that will be appropriate for the treatment of a wide range of conditions, such as fractures and sprains and post-operative support, prevent bedsores and allow inspection of various wounds. It provides a handy solution for the temporary support of an injured limb in field conditions while transporting a patient, for example, can also be used as a long term cast or bandage in the full course of treatment and may give postoperative support.

The said splint offers solutions for the setting and treatment of various areas of the body, such as the neck, the limbs, spinal and chest areas. It answers the basic need for a simple device, which is easy to use, handle, store and transport.

It is yet another object of the present invention to offer a practical solution to the needs of various medical teams such as hospital staff, EMS, health and care for the elderly, army and police emergency teams as well as private home use.

The invention describes a splint designed to allow for an adjustable and comfortable fit to different parts of the body which achieves maximum comfort and facilitates the recuperation period. It is a simply structured splint, which allows for uncomplicated assembly and operation. The splint is designed to fit the shape of the body part in need of treatment it provides support and wrapping for the injured area from three sides. The splint is made out of inflatable ribs. Using a hand pump or an air pressure source tank the ribs may be inflated to various degrees that provide the optimum support and comfort required for the particular conditions. Ventilation holes in the structure allow for sufficient airing and circulation of the limb and body part and the treated area. The splints are secured into place by Velcro straps.

The simplicity of the design and assembly enable the patients themselves to assemble and adjust the splint.

#### BRIEF DESCRIPTION OF THE DRAWINGS

These and further features and advantages of the invention will become more clearly understood in the light of the ensuing description of a preferred embodiment thereof, given by way of example only, with reference to the accompanying drawings, wherein-  
FIG. 1 is a perspective view of a first embodiment of the invention in an unassembled and uninflated condition;

FIG. 2 illustrates the first embodiment of the invention assembled on a leg.

FIG. 3 FIG. 3 is a cross-sectional view of the assembled splint shown in FIG. 2.

FIG. 4 FIG. 4 illustrates perspective view of a second embodiment of the invention in an unassembled and un-inflated condition.

FIG. 4 FIG. 5 illustrates a cross sectional view (section A) of the second embodiment as illustrated in FIG. 3 FIG. 4.

FIG. 5 FIG. 6 illustrates the second embodiment of the invention assembled on an arm.

FIG. 6 FIG. 7 illustrates a cross sectional view (section B) of the second embodiment as illustrated in FIG. 5 FIG. 6.

#### DETAILED DESCRIPTION OF THE INVENTION

The present invention is a new and simple medical device, aimed to help treat orthopedic conditions, by supporting and splinting immobilizing the injured body part in a desired position. It is a comfortable to wear lightweight device, which is simple, easy to assemble, water resistant and demands very little storage space. This is a multipurpose device facilitating emergency and long term treatments of different sorts of conditions.

The preferred embodiments of the invention are inflatable and adjustable, suited to fit different body part including the limbs, the chest, the torso, spine and the neck. The measure of air pressure inflating the device and the manner of fastening it around a body part are controllable and may be adjusted to suit the specific needs of any given condition. The device is made from a double layer of nylon coated by polyurethane, a flexible and a light weight material which is also strong and waterproof.

FIG. 1 offers a general description of the first embodiment of the invention, suited for leg injuries, in an unassembled condition. The splint 10 is comprised of a main body 20 and two or more unattached adjustable straps: [[an]]a front upper strap 6 and a front lower strap 7. When in use, parts 24, 25, 26a, 26b wrap the leg from three sides: part 24 holds the left side of the leg and part 25 the right side, while the back of the leg is wrapped by the splint central part 26a, 26b. Connecting Velcro surfaces 30 and 6 fastens the device around the calf. The lower right 40a and left part 40b of the splint wraps around the foot, while part 41 covers the sole of the foot. Attaching Velcro straps 31 to strap 7 on top of the foot and strap 42a to 42b at the sole fastens the lower part of the splint for supporting the lower part of the foot.

FIG. 2 illustrates the device as it is assembled on a leg 59.

Both the lower and the upper part of the splint have ventilating holes 52 to increase the comfort of long term use of the device, and at the edge of parts 40a, 40b, there are loops 50 which, if necessary, allow for suspending the leg raised up on a hook 55 to prevent it from swelling, as illustrated in FIG. 2. Parts 24, 25, 26, 40, 41 contain inflatable tubes. These tubes are designed to wrap the leg, the foot the ankle and the heel of the injured, taking into account the leg's curves and structure for maximum compatibility. Using the hand pump 16, which is connected to the said tubes through pipe 5 and valve 17, the tubes in the splint may be inflated. Alternatively, an air pressure source can be connected to valve 17 and used for the same purpose. Once inflated, valve 15 may be used to open the airways and let the air out of the tubes. Combining the effect of the hand pump 16 and the valve 15 allows for achieving the desired pressure in the tubes resulting in the required stiffness of the splint 10 around the leg, so that the support needed is maintained and the movement and flexibility of the leg is controlled without causing unnecessary discomfort. The pressure that the air tubes create on the leg does not obstruct the blood flow to the leg, and the ventilation holes 52 allow for sufficient airing of the area. When inflated, the splint takes up the shape of the part of the body for which it was designed as FIG. 3 illustrates.

Additional control over the amount of pressure and the tightness of the splint on the leg may be achieved by the fastening or loosening of the Velcro straps 6,7 to splint Velcro 30 and 31 respectively. In a different embodiment Velcro straps 6 and 7 are stitched to one of the sides of the splint body 20. As illustrated in FIG. 2 the patients can easily reach the said straps since they are on the front side of the leg, and has a convenient access to the pump so he or she can adjust level and volume of splint air pressure for themselves, to achieve maximum

results.

FIG. 3 illustrates a cross section of the splint as it is assembled on a leg 59. In this illustration it is easy to see that the splint is designed to fit the structure of the body part (the leg 59, in this example) and its joints.

The second embodiment of the invention is illustrated in FIGS. 3, 4, 5, 64, 5, 6 and 7. It is designed to be assembled on an arm. The principles guiding the structure of this embodiment are similar to those of the first embodiment; it differs from the first only to fit the structure and the treatment of a human arm.

~~FIG. 3~~ FIG. 4 illustrates the second embodiment in an unassembled state. The main body of the splint is divided into two parts: for supporting the upper part of the arm 61a (between the shoulder and the elbow) and of the lower part of the arm 61b (between the elbow and the wrists). Enclosing the main body 61 are Velcro straps 62, 63 which connect to each other when the device is assembled on an arm. The main part 61a contains an aperture for the shoulder 67 and the main part 61b includes an aperture for the palm 66 and a supporting surface for the palm and hand 65.

Like the main body of the first embodiment these two sections are both comprised of inflatable tubes which, when assembled on the arm, are designed to support the arm from three directions. ~~FIG. 4~~ FIG. 5 displays a cross-section of the splint when it is inflated and unassembled. This figure clearly shows the four tubes in the splint Velcro straps 62, 63 connect when the splint is assembled.

Also in ~~FIG. 3~~ FIG. 4 are the ventilating holes 68, similar to the ones on the first embodiment of this invention 52, and a support strap clip 64. This clip enables the attachment of straps that transfer the weight of the hand to the shoulders or to the waist. ~~FIG. 5~~ FIG. 6 illustrates the splint assembled on an arm. The figure displays the two options of attaching the supporting straps: a suspension strap 70 around the patient's neck and a strap wrapped around the waist 71.

The straps hook to the splint via the said clip 64.

~~FIG. 5~~ FIG. 6 also clearly illustrates the function of the aperture of the shoulder 67, the palm's aperture 66 and of the supporting surface for the palm 65. The structure of this embodiment of the splint is suited to hold the arm in a comfortable 90 degree angle at the elbow. ~~FIG. 6~~ FIG. 7 illustrates the cross section B of the assembled splint. This figure shows that the splint provides pressure and support to the arm from four directions.

Another embodiment of the present invention is a vest splint, designed to support the rib cage. The inflatable rib-tubes of the splint are aligned to follow the inclination of the rib bones and may be inflated in sections according to necessity. The vest is wrapped around the chest leaving two apertures for the arms and is fastened in the front by Velcro straps.

These unique designs of the splints as described allows for setting and stabilizing the injured body part while providing a controlled range of flexibility. Providing necessary support to the area and improving the course of treatment for better results.

While the above description contains many specificities, these should not be construed as limitations on the scope of the invention, but rather as exemplifications of the preferred embodiments. Those skilled in the art will envision other possible variations that are within its scope. Accordingly, the scope of the invention should be determined not by the embodiment illustrated, but by the appended claims and their legal equivalents.